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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/817,023	04/02/2004	Salvatore V. Pizzo	5405-304	2746

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EXAMINER	
LE, EMILY M	
ART UNIT	PAPER NUMBER
1648	
MAIL DATE	DELIVERY MODE
06/13/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/817,023	PIZZO ET AL.	
	Examiner	Art Unit	
	Emily Le	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04/02/04, 10/04/06+12/28/06*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *14-20* is/are pending in the application.

4a) Of the above claim(s) *20* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *14-19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *08/26/05+07/14/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election of Group II in the reply filed on 10/04/2006 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Status of Claims

2. Claims 1-13 and 21-27 are cancelled. Claims 14-20 are pending. Claim 20 is withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 10/04/2006. Claims 14-19 are under examination.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claim 17 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

To be enabling, the specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed invention without undue

experimentation. In Genentech *Inc. v. Novo Nordisk* 108 F.3d 1361, 1365, 42 USPQ2d 1001, 1004 (Fed. Cir. 1997); *In re Wright* 999 F.2d 1557, 1561, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993); See also *Amgen Inc. v. Chugai Pharm. Co.,* 927 F.2d 1200, 1212, 18 USPQ2d 1016, 1026 (Fed. Cir. 1991); *In re Fisher* 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970). Further, in *In re Wands* 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988) the court stated:

> Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized by the board in *Ex parte Forman* [230 USPQ 546, 547 (Bd Pat App Int 1986)]. They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

The claimed invention is directed at a method of inducing a prophylactic immune response in a subject with the administration of an immunogen and a mast cell activator, compound 48/80. The claims are not limiting to the type of prophylactic treatment.

Lines 13-15, page 14 of the specification discloses: **the present invention can be used prophylactically to prevent...bacterial infections, viral infections, fungal infections, parasitic infections and cancer.** Hence, in view of this disclosure, the breadth of the claims encompasses prophylactically, prevent, bacterial infections, viral infections, fungal infections, parasitic infections and cancer.

Additionally, the broadest and reasonable interpretation of the term infection merely requires that one microorganism gain entry into the cells of a host.

While the specification does contain working examples, however, none of the examples commensurate in scope with the claimed invention. At the very most, the working examples are directed at the induction of a therapeutic immune response with the use of a known immunogen and compound 48/80 as an adjuvant. However, there does not exist any working examples demonstrating or evidencing the induction of a prophylactic immune response. Furthermore, it should be noted that there is no evidence that entry of any microorganism is prevented.

Furthermore, the specification does not contain any guidance or direction directing the use of the claimed method as a prophylactic method. In the instant case, the specification is defective for a method of inducing a prophylactic immune response. Therefore, it is clear from the lack of evidence that the specification is not enabling for the claimed invention.

A conclusion of lack of enablement means that, based on the evidence regarding each of the above factors, the specification at the time the application was filed, would not have taught one skilled in the art how to make and/or use the full scope of the claimed invention without undue experimentation. *In re Wright*, 999 F. 2d 1557, 1562, 27 USPQ 2d 1510, 1513 (Fed. Cir. 1993).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 14-16 and 18-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mielcarek et al.[1]

The claims are directed at the concurrent administration of an immunogen and compound 48/80 to a subject to induce an immune response. Claim 15, which depends on claim 14, requires that the immunogen and compound 48/80 be administered simultaneously in a common pharmaceutical carrier. Claim 16, which depends on claim 14, requires that the administration be parenteral. Claim 18, which depends on claim 14, requires the immune response to be therapeutic. Claim 19, which depends on claim 14, requires the immune response to comprise a humoral immune response.

Lines 19-22, page 8 of the specification provides the following: **"Immunogen" and "antigen" are used interchangeably and mean any compound to which a cellular or humoral immune response is to be directed against.**

Mielcarek et al. teaches that compound 48/80 is a mast cell activator. Mielcarek et al. discloses that mast cells has been known to interact with certain pathogenic bacteria and present microbial immunogens to the immune system. [Abstract] Specifically, in an in vivo study, where Mielcarek et al. administered immunogen, *Bordetella pertussis*, *B pertussis* to the mice, Mielcarek et al. demonstrated that mast cells can efficiently phagocytose *B pertussis*. [Last paragraph, page 185]

[1] Mielcarek et al. Interaction of Bordetella pertussis with mast cells, modulation of cytokine secretion by pertussis toxin. Cellular Microbiology, March 2001, Vol. 3, No. 3, 181-188.

Mielcarek et al. does not teach the administration of a mast cell activator, compound 48/80, with the immunogen to enhance the immune response against the antigen.

However, it would have been prima facie obvious for one of ordinary skill in the art, at the time the invention was made, to administer compound 48/80 with the immunogen to the mice. One of ordinary skill in the art, at the time the invention was made, would have been motivated to do so enhance the immune responses against the immunogen. One of ordinary skill in the art, at the time the invention was made, would have had a reasonable expectation of success for doing so because the role of mast cell activators to present immunogens to the immune system is well known in the art.

Additionally, it would have been prima facie obvious for one of ordinary skill in the art, at the time the invention was made, to include a pharmaceutically acceptable carrier with compound 48/80 and the immunogen. One of ordinary skill in the art, at the time the invention was made, would have been motivated to do so to facilitate delivery of compound 48/80 and immunogen. One of ordinary skill in the art, at the time the invention was made, would have had a reasonable expectation of success for doing so because the use of pharmaceutically acceptable carriers are well known and practiced in the art.

Additionally, it would have been prima facie obvious for one of ordinary skill in the art to apply any one of these administration protocols. One of ordinary skill in the art, at the time the invention was made, would have been motivated to do so to facilitate administration of the immunogen and compound 48/80 to a subject. One of ordinary skill

in the art, at the time the invention was made, would have had a reasonable expectation of success for doing so because these administration protocols are well known and practiced in the art.

Lastly, it should be noted that Mielcarek et al. also teaches that the immunogen induced the release of proinflammatory cytokines and the production of IL-6 and 10, which indicate Th1 and Th2 immune responses, which are cellular and humoral immune responses, respectively.

Conclusion

7. No claims are allowed.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Emily Le whose telephone number is (571) 272 0903. The examiner can normally be reached on Monday - Friday, 8 am - 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce R. Campell can be reached on (571) 272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Emily M. Le/
Patent Examiner
Art Unit 1648

/E.Le/